

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, *ex rel.*
Cathleen Forney

Plaintiffs

v. MEDTRONIC, INC.
710 Medtronic Pkwy NE
Minneapolis, MN 55432

Defendant.

Civil Action No. 5:15-cv-6264-EGS

***MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF RELATOR'S
MOTION TO AMEND AND TO LIFT STAY OF DISCOVERY***

By Memorandum Opinion and Order dated June 19, 2017, the Court held that Relator had failed to state a claim, and directed that this lawsuit be dismissed without prejudice. Relator has prepared a proposed Second Amended Complaint (appended as Exhibit A to the Accompanying Memorandum of Points and Authorities), which Relator respectfully submits corrects the deficiencies identified by the Court.

First, the Court held that the Relator had failed to allege with sufficient particularity how the free services constituted illegal remuneration under the Anti-Kickback Statute. *See* Memorandum Opinion, Dkt. No., 37 (dated June 19, 2017) at 9-10. The Court required Relator “to describe with sufficient specificity” how Medtronic’s free services constituted “illegal remuneration with independent value to the purchaser.” Relator’s proposed Second Amended Complaint (“SAC”) adds a significant amount of additional detail to illuminate why Medtronic’s free services constitute illegal

remuneration. The proposed SAC includes substantial additional factual allegations and quotes extensively from Medtronic documents to illuminate how Medtronic directed its Clinical Specialists¹ to call on health care providers without being asked. Obviously, if Medtronic were merely providing needed product support, it would await a customer request. Further, the Clinical Specialists make far more calls than may be explained by supporting the implant of a new and complex device. Presumably, such a troubleshooting service call would be made once or perhaps twice. But Medtronic sends its Clinical Specialists to health care providers literally *thousands* of times per implanted device.

Relator also provides additional information about the market value of all these free services. If a health care provider had to obtain the service in the free market, it would be paying anywhere from \$17 to \$22 per hour to \$35,000 to \$40,000 per year. In short, Medtronic is not transferring de minimis value to the health care providers; it is transferring significant and substantial value independent of the product.

Relator also explains that Medtronic provided a litany of free services not even superficially connected in any way to the devices, such as consulting on reimbursement, practice management and the payment of background checks for credentialing.

Second, the Court held that Relator had failed to allege Medtronic acted knowingly and willfully. See Dkt. No. 37 at 10. *See, e.g., U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3rd Cir. 2004); *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 674 (W.D. Pa. 2014). Relator added substantial additional factual

¹ At oral argument, Relator's Counsel could not recall the name given to those providing service, but speculated it was Service Representatives. In fact, the term Medtronic uses to identify those that provide free services is Clinical Specialist.

allegations showing that Medtronic knew its conduct violated the law. Medtronic actually disseminated a booklet to all its employees that shows clear knowledge. In this booklet, non-permissible conduct was defined as “perform routine clinic, office, administrative or professional tasks.” That is precisely the type of services being provided by Medtronic. And even more compelling, Medtronic paid \$40 million to settle a lawsuit in which one of the United States’ allegations was that Medtronic’s Spine division violated the Anti-Kickback Statute by providing free services. In addition, given that Ms. Forney served as Medtronic management, her knowledge that the free services constituted kickbacks should be imputed to Medtronic.

Third, the Court held that Relator had not met the particularity requirement with respect to conduct outside of Pennsylvania. See Kdt. No. 37 at 11-12. Relator’s proposed Second Amended Complaint adds a significant amount of detailed factual allegations, explaining that Medtronic deployed the Clinical Specialists in the same fashion across the nation. In addition, Relator identified health care providers who were paid Medtronic kickbacks in each of the Plaintiff States.

Because the Relator provided these free services, supervised Clinical Specialists, and worked with Corporate on nationwide projects relating to these kickbacks, she has extensive and detailed knowledge of the Medtronic’s wrongdoings. Relator believes that the proposed Second Amended Complaint sets forth all the missing details desired by the Court, but of course stands ready to provide even more detail in the event the Court disagrees.

The Relator respectfully asks that the Court hold that the proposed Second Amended Complaint corrects all the identified deficiencies, and lift the pending stay on discovery.

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